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JOHN T. FEY, Clerk

IN THE

Supreme Court of the United States

OCTOBER TERM, 1956.

No. 309

2600 STATE DRUGS, INC., a corporation,
EDWARD KRAVETZ,
MELBURN HOLTZMAN,
RAYMOND HOLTZMAN,

Petitioners,

vs.

THE UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

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The Scheffer Press, Inc.—ANdover 3-6850

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1956.

No.

2600 STATE DRUGS, INC., a corporation,
EDWARD KRAVETZ,
MELBURN HOLTZMAN,
RAYMOND HOLTZMAN,

Petitioners,

vs.

THE UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

To The Honorable, The Chief Justice And Associate Justices Of The Supreme Court Of The United States:

The Petitioners pray that a writ of certiorari be issued to review the decision of the United States Court of Appeals for the Seventh Circuit in the above case.

QUESTIONS PRESENTED.

1. Where local sales were made of drugs which had been received from interstate commerce and the federally prescribed labels were preserved intact at the time of sale and no misbranding existed in fact, could Congress provide that such sale, if made without prescription, would be deemed a sale of a "misbranded" article so as to invoke the criminal sanction against the sale of misbranded drugs?

2. Is the statute (title 21 Sections 353 (b), (c), (i), (iii) which has enlarged the term "misbranded" to include acts having no relation to the label, merely a means of prescribing a penalty or is it an improper and unconstitutional method of enlarging a crime so as to embrace acts purely local in nature?

JUDGMENT OF THE COURT BELOW.

The judgment of the United States District Court for the Northern District of Illinois, Eastern Division, was entered on October 3, 1955 and is not reported but appears in the record filed with and certified by the Clerk of the Court of Appeals and is transmitted herewith.

The record was not printed for the use of the Court of Appeals, but was considered on the typewritten stenographic transcript and certified record of the trial Court.

The opinion of the United States Court of Appeals for the Seventh Circuit, affirming the said judgment was filed July 11, 1956 and is not yet reported but is set forth in the Appendix hereto and in the certified copy of the Record.

The principal point raised by petitioners in the Court of Appeals concerned the constitutionality of the Durham-Humphrey Amendment as it concerned the use of the commerce power. This point is first considered by the Court of Appeals below in its opinion at pp. 5a-6a in the Appendix hereto. It is unfortunate that the secondary point raised on appeal below was characterized by the Court as the principal point of petitioners (App. 1a), particularly since the only matter argued before the Court was the interference with the reserve powers under the Tenth Amendment.

JURISDICTION.

On Wednesday, July 25, 1956, the United States Court of Appeals for the Seventh Circuit granted a stay of mandate of 30 days from the date of affirmance to enable the Petitioners herein to file their petition for certiorari. This petition is filed within the 30 days alloted. The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254 (1) 62 Statutes 928.

STATEMENT OF THE CASE.

The petitioners were convicted for violations of the Food and Drug Act, Sections 353 (b) and 331 (k) of Title 21 U S C.

The defendants sold tablets of two kinds; racemic amphetamine sulfate (Benzedrine) and sulfasoxazole in the bottles which had been received from the manufacturer. Although the labels which bore federally prescribed legends were intact and undisturbed on the bottles at the time of sale, the articles were deemed to be misbranded because they were sold without prescription. Motions to dismiss were filed to the indictment and were overruled. Upon a trial the defendants were found guilty. The corporate defendant, an Illinois corporation, was fined $250.00 on each of four counts cumulatively. Edward Kravetz was sentenced to three months in the custody of the Attorney General and fined $250.00 on Counts I and II. Raymond Holtzman was sentenced to three months in the custody of the Attorney General and fined $250.00 on Counts I and II, and Melburn Holtzman was sentenced to three months in the custody of the Attorney General and fined $250.00 on Counts I and II.

PERTINENT STATUTES.

The statutes with the applicable portions italicized read as follows:

Title 21, Section 331.

"The following acts and the causing thereof are hereby prohibited:

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, *or the doing of any other act* with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." (italics supplied).

Title 21, Sec. 353.

Prescription By Physician; Exemption From Labeling And Prescription Requirements; Misbranded Drugs; Compliance With Narcotic And Marihuana Laws—

(b) (1) A drug intended for use by man which—

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under Section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug.

shall be dispensed only (i) *upon a written prescription of a practitioner licensed by law to administer such drug,*

or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. *The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.* (italics supplied)

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

(X Amendment, United States Constitution).

REASONS FOR GRANTING WRIT.

This case is important because it concerns a new concept in the use of the commerce power and is based upon the improper construction of a prior decision of this Court, *United States* v. *Sullivan*, 332 U.S. 689. In that case this Court approved a statute which forbade the local sale of a drug which had been received from interstate commerce where the label failed to bear adequate directions for use. (Section 352 (f) of the former Act under which Sullivan was tried has its counterpart in 353 (b), of the present Act, save for the addition complained of here).

In that case, Sullivan, a Druggist, had removed the label prior to sale of the drug and this removal was held to be the equivalent of obliteration; thus, an act which resulted in the article being misbranded. The Supreme Court held further that such a sale was punishable even though the goods might have come to rest for a long period of time and that the integrity of the label could be preserved through each such sale.

Armed with what it considered a greater authority over local sales of drugs, Congress passed the Durham-Humphrey Amendment to the Food and Drug Law in 1951, but it added a new definition of misbranding which had not been before the court in the *Sullivan* case.

This Act divided drugs into two categories "prescription" and "over-the-counter" and forbade the sale of the former without prescription. It provided that such a sale without prescription would be deemed to be a holding for sale of a "misbranded" article (Section 353 (b), although the article was not misbranded in fact.

It is believed that in Section 353 (b) 1 Congress attempted through the use of a legislative fiction, *i.e.,* calling a true label false, to accomplish indirectly what it could not do directly and that it attempted thereby to assume jurisdiction over a local act which it had no power to do.

It is contended for the petitioners herein that while Congress may forbid the channels of interstate commerce to debased or falsely labeled articles, that it may not in the absence of such conditions, regulate the practice of pharmacy by requiring prescriptions as a condition of sale.

Although the various food and drug acts have been liberally construed, Congress' power to regulate foods and drugs has not been considered to be without limitation. The Supreme Court was mindful of the area in which Congress might not legislate when it spoke in the case of *Hoke* v. *United States,* 227 U.S. 308, 321, saying:

> "We may illustrate again by the Pure Food and Drugs Act. Let an article be debased by adulteration, let it be misrepresented by false branding, and Congress may exercise its prohibition power. It may be that Congress could not prohibit the manufacture of

> the article in a state. It may be that Congress could not prohibit in all of its conditions its sale within a state. But Congress may prohibit its transportation, etc. * * *"

What was there in the *Sullivan* decision or in the cases which preceded it which would justify the power exercised here? In the past, the regulation of foods and drugs has concerned protection of the consumer against debasement of the product and misinformation concerning it and nothing more. In the case of *McDermott* v. *Wisconsin,* 228 U.S. 115, and in the *Sullivan* case which relied on it, the determining factors were simply stated by Mr. Justice Black in the *Sullivan* case when he said "In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the *branding* of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce". (p. 698) (emphasis supplied)

If there be any novelty in the decision of the *Sullivan* case, it is that the Court held that no matter how numerous successive transfers might be of a drug which had originated in interstate commerce, the integrity of the label would have to be preserved so that no one should keep it from the eyes of the consumer. Significantly, the entire opinion is wanting in any approval of a prohibition *dehors* the product. If there is any doubt that it was the label itself which was the determining factor, the following brief quotation from the opinion of the Court should suffice to emphasize this:

> "Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which section 502 (f) requires. There is a suggestion here

> that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a "misbranding," transferring the pills to non-branded boxes would not have been, so long as the labeling on the emptly bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act." (P. 695)

This same emphasis on the label as distinguished from the sale itself was made in a case which arose immediately after the Durham-Humphrey Amendment was passed.

In the case of *United States* v. *El-O-Pathic Pharmacy*, 192 F. 2d 62 (CCA 9) (1951), a drug had been received by a seller with rather substantial directions for use including the phrase, "Caution—to be used only by or on the prescription of a physician." The seller retained all the directions for use save this one phrase which he struck out.

The United States sued to restrain the transmission of the drug in interstate commerce and to enjoin its sale, citing Section 331 (k) as a basis for the allegations that the drug had been misbranded. After a review of the nature of the product, the Court referred to *United States* v. *Sullivan*, saying:

> "A liberal interpretation of the Act, having in mind its background and purposes, requires us to sustain the action of the Administrator on the ground that he was empowered, under the statute, to exempt by regulation the drugs in question from the requirement that the label bear adequate instructions for use, con-

ditioned upon *its bearing an inscription* that it be used only on the prescription of a physician. Under such construction, the regulation is not contrary to to law, arbitrary, or unreasonable. *This is not the same as conferring upon the Administrator a general authority to create classes of drugs or to specify the manner in which drugs of each class are sold,* as argued by appellees; but where no adequate directions for use of specified dangerous drugs can be written for purposes of self-medication by a layman, and they can be safely taken only upon the advice and under the supervision of a physician, it is within the statutory power conferred upon the Administrator to require, by regulation, that *the label* set forth that they be taken only upon prescription of a physician. From another viewpoint, it would seem, from the evidence, that, aside from the regulation, the only adequate direction for use of the drug in question would be a requirement that it be taken only on the prescription of a physician and that, *in default of a label embodying such direction,* the drug would be misbranded under the statute." (italics supplied)

The substantial factual differences between the *Sullivan* case and the instant case furnish a key to the vice in the statute. First, Sullivan actually removed the label so that the purchaser never saw it. In the instant case the label bearing directions and warnings was undisturbed and was on the bottles at sale. Secondly, Sullivan was tried for having sold an article which lacked adequate directions for use. In the instant case petitioners were tried for having sold an article without requiring a prescription.

Section 353 (b) was recently considered by the Court of Appeals for the 5th Circuit in *United States* v. *Carlisle* (decided May 31, 1956, and not yet reported in the Federal 2nd Reporter). On the facts the case is fairly close since the misbranding was charged to have derived from the refilling

of a drug without prescription or authority. Unhappily, the Court did not have before it a clear question with regard to the constitutionality of the statute. The attack on the indictment was that it was duplicitous. It was the opinion of the Court that in calling the drug dispensed without prescription "misbranded", Congress had merely selected "an unduly awkward way of getting about charging an offense". The Court stated that Congress had merely selected a method of fixing a penalty for the Act by setting it out in a section carrying the prohibition.

It is submitted that nothing in the Act nor in the hearings which preceded its passage would suggest that the language used was merely a means of prescribing a penalty. The fiction ascribed to the label was obviously a device to bring the new statute into square with the doctrine restated in the *Sullivan* case, for without this fiction, the prohibition against sale without prescription would stand alone.

Does Congress have jurisdiction without reference to the integrity of the label, to prohibit the local sale of a drug under the commerce power? Such a regulation has been sustained heretofore only under the power to tax, as in the case of narcotics. The difference between the power over commerce and the power to tax is still vigorous today. A recent attempt to equate one with the other as a means of justifying the regulation of local matters was rejected by the Supreme Court when it said in the case of *United States* v. *Five Gambling Devices,* 344 U.S. 444, 448,

> "Of course, decisions upholding legislation requiring information in aid of the taxing power afford no support here, because the taxing power penetrates and permeates every activity intrastate or interstate, within the Nation."

It may be conceded that Courts have acquiesced in an apparently unlimited power in Congress to regulate matters previously regarded as of only local concern, such as farm production, working conditions and industrial relations.

Wickard v. *Filburn,* 317 U.S. 111 (1942);
United States v. *Darby,* 312 U.S. 100 (1941);
N.L.R.B. v. *Jones & Laughlin Steel Corp.,* 301 U.S. 1 (1937).

But in each of these cases regulation was shown to be necessitated by the relation of local activities to the conduct of commerce as a whole, the preservation and promotion of which was said to be the objective of the statute in question.

This same connection to interstate commerce is not claimed for the statute before us. Admittedly, the local retail sale of drugs produces no such demonstrable effect upon the vitality of national commerce as do over-production, low wages and industrial strikes.

Indeed, it was argued below without reply and nowhere in the legislative history of the Act is it asserted, that the local sales of drugs had any effect on commerce which would justify regulation.

Congress has a right to legislate by definition if it chooses. As illustration, it might say, in expanding the application of inspection requirements covering steam vessels, that vessels propelled by any form of mechanical or electrical power "shall be considered steam vessels within the meaning * * * of this act." (*Ace Waterways* v. *Fleming,* 98 F. Supp. 666, 667.) This, of course, is a typical instance where legislation by definition is lawful because it falls within the constitutional authority of Congress to legislate with respect to the inspection of vessels in the first instance.

However, the mere fact that Congress has chosen to call a true label false does not make it so.

The Supreme Court's opinion in the *Sullivan* case is admittedly the basis for the amendment complained of herein. The Court of Appeals affirmed in reliance on its principle, without, however, discussing its applicability. Nothing in the Supreme Court's opinion, however, will justify the method employed by Congress in this instance. Congress, though free in the enactment of statutes to make definitions of its own, has heretofore not been permitted to use this device to enlarge its constitutional authority. If the exercise of power herein is sustained, then Congress has been granted a free hand to disregard not only the Tenth Amendment but every other Amendment to the Constitution, since it is a very easy matter to call one act another, or one object another and thereby bring it within the condemnation of a statute as "reasonable implementation".

CONCLUSION.

It is trite, but necessary, to say once again that worthy motive may not of itself support enlargement of a constitutional power. It may be that the desire to compel the citizenry to seek out its physicians is either wholly beyond the authority of government or must be left to the States which licenses both pharmacists and physicians. There may come a time when the People of the United States will amend the Constitution and abrogate their local fiat and elect to be governed solely by a National Government. If this should come, it ought to be by choice and not by the too easily contrived device of the legislative fiction.

Respectfully submitted,

BERNARD H. SOKOL
Attorney for Petitioners.

APPENDIX.

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

No. 11654. OCTOBER TERM, 1955, APRIL SESSION, 1956.

UNITED STATES OF AMERICA,
Plaintiff-Appellee,
vs.
2600 STATE DRUGS, INC., EDWARD KRAVETZ, MELBURN HOLTZMAN and RAYMOND HOLTZMAN,
Defendants-Appellants.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

July 11, 1956

Before DUFFY, *Chief Judge,* LINDLEY and SWAIM, *Circuit Judges.*

SWAIM, *Circuit Judge.* The defendant 2600 State Drugs, Inc., and the individual defendants, Edward Kravetz, Melburn Holtzman and Raymond Holtzman, all of whom were either officers or employees of the defendant drug corporation, were charged in a criminal information with having sold, without a prescription, certain drugs in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. Section 301, *et seq.* In a trial before the District Court all of the defendants were found guilty of violating the Act.

The principal question presented by this appeal is whether or not those sections of the Federal Food and Drug Act which prohibit the sale of dangerous drugs without a prescription are sufficiently definite to give reason-

able notice to persons bound by the proscriptions of the Act and subject to its penalties.

The applicable parts of Section 331 of 21 U.S.C.A. provide:

"Prohibited acts

"The following acts and the causing thereof are hereby prohibited:

"(b) The adulteration or misbranding of any * * * drug * * * in interstate commerce.

* * *

"(k) The adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or *the doing of any other act* with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." (Our emphasis.)

Section 353 of 21 U.S.C.A., concerning prescriptions by physicians, prescription requirements and the misbranding of drugs, provides:

"(b)(1) A drug intended for use by man which—

* * *

"(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

"(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug * * *. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

* * *

"(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at

any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription.' * * *"

Section 355 of 21 U.S.C.A., concerning new drugs and the necessity of effective application, provides:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

"(b) Any person may file with the Secretary [of Health, Education and Welfare] an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; * * * and (6) specimens of the labeling proposed to be used for such drug."

At the beginning of the trial of this case the parties stipulated that the drugs which the defendants were accused of dispensing without a prescription were drugs within the meaning of 21 U.S.C.A. Section 353(b)(1)(B), as amended, and which prior to January 16, 1954, were shipped in interstate commerce into the State of Illinois and were held in the manufacturer's original labeled bottle, the label upon which included the statement, "Caution: Federal Law Prohibits Dispensing Without Prescription."

In this case the evidence in the record furnished a sufficient basis for the finding of the trial court that the drugs in question could be safely used only under the direction and supervision of a physician and that the defendants dispensed said drugs without prescriptions, as charged in the information.

Although admitting that the drugs here in question had been shipped in interstate commerce, that the container carried a label stating that federal law prohibited the sale of the drugs without a prescription, and that there was sufficient evidence to support the trial court's finding that the defendants had made sales of such drugs without prescriptions, the defendants insist that the language of the

statute is so vague, uncertain and indefinite as to fall short of the constitutional requirements of due process of law. On this point the defendants contend that the statute here in question is so vague and indefinite "that men of common intelligence must necessarily guess at its meaning and differ as to its application," and that, therefore, the statute is too vague, indefinite and ambiguous to constitute a legal basis for a criminal charge. We think the provisions of this Act are sufficiently definite to support a criminal charge for the violation of the Act.

In *Boyce Motor Lines* v. *United States,* 342 U.S. 337, the Court was considering the validity of a regulation promulgated by the Interstate Commerce Commission which provided that drivers of motor vehicles transporting certain explosives and poisonous gases should "avoid, so far as practicable, and where feasible, by prearrangement of routes, driving into or through congested thoroughfares, places where crowds are assembled, street car tracks, tunnels, viaducts, and dangerous crossings." In its opinion in that case the Court said (page 340):

> "A criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation. But few words possess the precision of mathematical symbols, most statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions. Consequently, no more than a reasonable degree of certainty can be demanded. Nor is it unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line."

In *Sproles* v. *Binford,* 286 U.S. 374, the Court was considering a Texas statute which prohibited the carriage of overweight and oversize loads by commercial carriers but which permitted the granting by the State Highway Department of permits, for ninety days, for the carrying of such loads "as cannot be reasonably dismantled." The

statute provided further that these loads were to be carried "by the shortest practicable route." The Court there held (page 393) that the phrase, "shortest practicable route," was not an expression too vague to be understood. The Court explained:

> "The requirement of reasonable certainty does not preclude the use of ordinary terms to express ideas which find adequate interpretation in common usage and understanding. [Citing authorities.] The use of common experience as a glossary is necessary to meet the practical demands of legislation. In this instance, to insist upon carriage by the shortest *possible* route, without taking the practicability of the route into consideration, would be but an arbitrary requirement, and the expression of that which otherwise would necessarily be implied, in order to make the provision workable, does not destroy it." 288 U.S. at page 393.

Another factor which we must consider in the instant case is the fact that the provisions of the sections of the Act here under consideration were to bind *pharmacists* and to subject them to penalties in case of violations.

To ship these drugs in interstate commerce it was necessary for the manufacturer to qualify them pursuant to the requirements of Section 355 of the Act. The drugs were qualified for interstate shipment on the condition that the container in which they were shipped bear a label which read, "Caution: Federal law prohibits dispensing without prescription." Section 331(k) of the Act prohibited the removal of this label. The evidence here showed that when the sales of these drugs were made the label on the container was intact. It would seem clear that any pharmacist who sold these drugs without a prescription would necessarily know that he was violating the Food and Drug Act but that in order to make such sales the defendants were willing to defy the prohibitions of the Act.

The defendants also insist that that part of Section 353 (b)(1)(C) of the Act which provides that "The act of dispensing a drug contrary to the provisions of this paragraph [without the prescription of a physician] shall be

deemed to be an act which results in the drug being misbranded while held for sale," goes beyond the purpose of the Food and Drug Act, the sole purpose of which is to inform and so protect the ultimate consumer that he may be guarded against misrepresentation. The defendants say that the arbitrary extension of the meaning of the word "misbranded" constitutes an unreasonable exercise of the commerce powers of Congress and violates the Fifth and Tenth Amendments of the Constitution of the United States. This contention we think is answered in *United States* v. *Carlisle* (No. 15898, 5 Cir., ... F. 2d ....., which was decided May 31, 1956. The court in the *Carlisle* case pointed out that the Act sets out the only way the drugs there in question could be dispensed and then goes on to say that the act of dispensing the drugs contrary to the provisions of the Act shall be deemed to be an act which results in the drug being misbranded. The court there said (page 6 of the slip opinion):

> "This established, by law in this section, there is required only resort to 21 U.S.C. 331(k), which denounces the offense of misbranding, and to Sec. 333, which fixes the penalty for that offense."

The court concluded:

> "* * * that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353 (b)(1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding."

The court there held (page 7 of the slip opinion):

> "* * * that the use of the word 'deemed' in the act creates an irrebutable presumption, a rule of substantive law, and that the doing of the prohibited act, dispensing the drugs * * * without the authorization of the prescriber, makes refilling misbranding and subjects the dispenser to the penalties provided for misbranding."

The defendants also insist that the sales of these drugs without prescriptions constituted purely intrastate transactions, that these drugs did not remain a part of the

stream of interstate commerce, and that the sales of the drugs at retail did not affect interstate commerce directly or indirectly. In support of this contention the defendants cite *Schechter Corp.* v. *United States,* 295 U.S. 495, 544. But we think this contention is answered in *United States* v. *Sullivan,* 332 U.S. 689. In the latter case the defendant Sullivan, a retail druggist in Columbus, Georgia, purchased from a wholesale druggist in Atlanta, Georgia, a bottle of sulfathiazole tablets which had been shipped in interstate commerce from Chicago, Illinois. The label on the bottle which the defendant received gave adequate directions for the use of the tablets and adequate warning to protect the ultimate consumer from dangers incident to their use. The defendant removed some of the tablets from the original labeled bottle and placed them in a pill box labeled with the name of the drug but without adequate directions for use or warnings of danger. The Court there, after pointing out that the defendant had bought the drugs over six months after the interstate commerce shipment to the purchaser in Atlanta had been completed, said (pages 696 and 697):

> "But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of § 301(k) [§ 331(k) of the present Act]. '* * * The words of paragraph (k) 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap [left by paragraphs (a), (b) and (c)] and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.''

In the *Sullivan* case the Court rejected the contention that its holding permitted Congress to invade the powers reserved by the Constitution to the states, pointing out

that it had held in *McDermott* v. *Wisconsin*, 228 U.S. 115, that the authority of Congress to make such requirements was a proper exercise of its powers under the commerce clause.

We think that the principles announced by the Court in the *Sullivan* and *McDermott* cases require us to hold here that Congress properly exercised its powers under the commerce clause by providing that drugs which have been transported in interstate commerce and which are dangerous to human beings unless their use is prescribed by a physician should not be dispensed except on the prescription of a physician.

The judgment of the District Court is AFFIRMED.

APPENDIX.

F.D.C. No. 36614

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS; EASTERN DIVISION

UNITED STATES OF AMERICA
v.
2600 STATE DRUGS, INC., a corporation, and EDWARD KRAVETZ, RAYMOND HOLTZMAN, MELBURN HOLTZMAN, individuals

No. 55 CR 26
(21 U.S.C. 331 and 333)

COUNT I (58-808 L)

The United States Attorney charges:

That prior to January 16, 1954, a number of racemic amphetamine sulfate tablets, a drug within the meaning of 21 U.S.C. 353(b)(1)(B) as amended, were shipped in interstate commerce into the State of Illinois, in a bottle labeled in part as follows:

> Caution—Federal law prohibits
> dispensing without a prescription

That thereafter, on or about January 16, 1954, and while a number of tablets of said drug in said bottle were being held for sale after shipment in interstate commerce, as aforesaid, at the 2600 State Drugs, Inc., 2600 South State Street, Chicago, Illinois, the said 2600 State Drugs, Inc., a corporation organized and existing under the laws of the State of Illinois, and trading and doing business at Chicago, Illinois, and Edward Kravetz, an individual, at the time hereinbefore mentioned vice president, director, employed as manager of the drug department and pharmacist of 2600 State Drugs, Inc., the defendants herein, did, at Chicago, Illinois, within the Eastern Division of the Northern District of Illinois, cause said

tablets of said drug in said bottle to be dispensed to one William M. Chaffee, without a prescription therefor from a practitioner licensed by law to administer said drug;

That said act of causing the dispensing of said drug, as aforesaid, was an act caused to be done by said defendants, contrary to the provisions of 21 U.S.C. 353(b)(1), which resulted in said drug in said bottle being misbranded while held for sale, in violation of Title 21, United States Code, Section 331 (k).

COUNT II

(58-809 L)

The United States Attorney further charges:

That prior to February 3, 1954, a number of racemic amphetamine sulfate tablets, a drug within the meaning of 21 U.S.C. 353(b)(1)(B) as amended, were shipped in interstate commerce into the State of Illinois, in a bottle labeled in part as follows:

Caution—Federal law prohibits
dispensing without a prescription

That thereafter, on or about February 3, 1954, and while a number of tablets of said drug in said bottle were being held for sale after shipment in interstate commerce, as aforesaid, at the 2600 State Drugs, Inc., 2600 South State Street, Chicago, Illinois the said 2600 State Drugs, Inc., a corporation, organized and existing under the laws of the State of Illinois and trading and doing business at Chicago, Illinois, and Edward Kravetz, an individual, at the time hereinbefore mentioned vice president, director, employed as manager of the drug department and pharmacist at 2600 State Drugs, Inc., the defendants herein, did, at Chicago, Illinois, within the Eastern Division of the Northern District of Illinois, cause said tablets of said drug in said bottle to be dispensed to one William M. Chaffee, without a prescription therefor from a practitioner licensed by law to administer said drug;

That said act of causing the dispensing of said drug, as aforesaid, was an act caused to be done by said defendants, contrary to the provisions of 21 U.S.C. 353 (b) (1), which resulted in said drug in said bottle being misbranded while held for sale, in violation of Title 21, United States Code, Section 331 (k).

COUNT III

The United States Attorney further charges:

The prior to February 17, 1954, a number of racemic amphetamine sulfate tablets, a drug within the meaning of 21 U.S.C. 353(b)(1)(B) as amended, were shipped in interstate commerce into the State of Illinois, in a bottle labeled in part as follows:

Caution—Federal law prohibits
dispensing without a prescription

That thereafter, on or about February 17, 1954, and while a number of tablets of said drug in said bottle were being held for sale after shipment in interstate commerce, as aforesaid, at the 2600 State Drugs, Inc., 2600 South State Street, Chicago, Illinois, the said 2600 State Drugs, Inc., a corporation organized and existing under the laws of the State of Illinois, and trading and doing business at Chicago, Illinois, and Raymond Holtzman, an individual, at the time hereinbefore mentioned employed as a part time clerk of the drug department of 2600 State Drugs, Inc., the defendants herein, did, at Chicago, Illinois, within the Eastern Division of the Northern District of Illinois, cause said tablets of said drug in said bottle to be dispensed to one Robert W. Case, without prescription therefor from a practitioner licensed by law to administer said drug;

That said act of causing the dispensing of said drug, as aforesaid, was an act caused to be done by said defendants, contrary to the provisions of 21 U.S.C. 353(b)(1), which resulted in said drug in said bottle being misbranded while held for sale, in violation of Title 21, United States Code, Section 331 (k).

COUNT IV

(33-514 L)

The United States Attorney further charges:

That prior to February 24, 1954, a number of sulfisoxazole tablets, a drug within the meaning of 21 U.S.C. 353 (b)(1)(c) as amended, were shipped in interstate commerce into the State of Illinois, in a bottle labeled in part as follows:

Caution—Federal law prohibits
dispensing without a prescription

That thereafter, on or about February 24, 1954, and while a number of tablets of said drug in said bottle were being held for sale after shipment in interstate commerce, as aforesaid, at the 2600 State Drugs, Inc., 2600 South State Street, Chicago, Illinois, the said 2600 State Drugs, Inc., a corporation organized and existing under the laws of the State of Illinois, and trading and doing business at Chicago, Illinois, and Melburn Holtzman, an individual, at the time hereinbefore mentioned secretary treasurer, director, employed as part time clerk of the drug department and apprentice pharmacist of 2600 State Drugs, Inc., the defendants herein, did, at Chicago, Illinois, within the Eastern Division of the Northern District of Illinois, cause a number of tablets of said drug in said bottle to be dispensed to one William M. Chaffee, without a prescription therefor from a practitioner licensed by law to administer said drug;

That said act of causing the dispensing of said drug, as aforesaid, was an act caused to be done by said defendants, contrary to the provisions of 21 U.S.C. 353(b)(1), which resulted in said drug in said bottle being misbranded while held for sale, in violation of Title 21 United States Code, Section 331 (k).

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United States Attorney for the Northern District of Illinois.

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In the Supreme Court of the United States

OCTOBER TERM, 1956

No. 309

2600 STATE DRUGS, INC., A CORPORATION, EDWARD KRAVETZ, MELBURN HOLTZMAN, RAYMOND HOLTZMAN, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App. 1a–8a) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals (Pet. App. 1a–8a) was entered on July 11, 1956. The petition for a writ of certiorari was filed on August 10, 1956. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1).

QUESTION PRESENTED

Whether, under its power to regulate commerce, Congress can prohibit the intrastate sale-without-

prescription of dangerous drugs which have been shipped in interstate commerce and held for sale.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, as amended, 21 U. S. C. 301 et seq., provides in pertinent part:

> 21 U. S. C. 331. *Prohibited acts.*
>
> The following acts and the causing thereof are prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.
>
> * * * * *
>
> 21 U. S. C. 333. *Penalties—(a) Violation of section 331.*
>
> Any person who violates any of the provisions of section 331 of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * * .

21 U. S. C. 353 (b) *Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.*

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352 (d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

STATEMENT

Petitioners were found guilty by the District Court for the Northern District of Illinois, sitting without a jury, on an information (Pet. App. 9a–12a) which

charged the sale, without prescription, of drugs bearing on their container the legend, "Caution, federal law prohibits dispensing without prescription", contrary to the provisions of 21 U. S. C. 353 (b) (1), *supra*, p. 3, which act resulted in the drugs being misbranded while held for sale in violation of 21 U. S. C. 331 (k), *supra*, p. 2 (R. 1053–1054). The corporate petitioner was fined $250 cumulatively on each of the four counts of the information; the individual petitioners were each sentenced to a total of three months' imprisonment and fined $250 cumulatively on the counts naming them (R. 1066–1068).

Petitioners do not contest here, nor did they before the Court of Appeals, the finding of the district court that they had violated the terms of the statute. They argue that Congress exceeded its authority to regulate commerce when it proscribed an intrastate sale-without-prescription of dangerous drugs that had been shipped in interstate commerce. The Court of Appeals overruled this contention on the authority of *United States* v. *Sullivan*, 332 U. S. 689, and *McDermott* v. *Wisconsin*, 228 U. S. 115 (Pet. App. 6a–8a).[1]

ARGUMENT

The constitutional issue presented by this case, whether Congress can, under its power to regulate interstate commerce, penalize the local sale-without-prescription of a dangerous drug which has been shipped through the channels of interstate commerce,

[1] The Court of Appeals also dismissed petitioners' argument that the statute was unconstitutionally vague (Pet. App. 1a–6a), and petitioners do not contest that holding here.

has been affirmatively answered by this Court in *United States* v. *Sullivan*, 332 U. S. 689, 696–698, which upheld a criminal sanction imposed under the Federal Food, Drug, and Cosmetic Act against a local sale of a dangerous drug which had not been adequately labeled.

Petitioners' attempt to distinguish the *Sullivan* decision (Pet. 7–8) on the ground that it involved mislabelling of the article itself, whereas here the article sold did carry proper labelling, the misbranding resulting from the act of selling without prescription.[2] But, while the *Sullivan* decision does refer to misbranding because the violation there charged was misbranding, the constitutional problem arising from the fact of local sale is not different. In the *Sullivan* case, as here, the article involved had been properly labeled during its interstate shipment. The constitutional question before the Court was whether congress had the power to prevent a local druggist from taking pills out of the properly shipped bottle and selling them locally without proper labelling. When the Court held that Congress had such power, it necessarily decided the question here involved—*i. e.*, that Congress could forbid the sale entirely, without prescription.

The constitutional basis upon which the statutes in both the *Sullivan* case and this case rest is the power

[2] The *Sullivan* decision was handed down prior to the Durham-Humphrey amendment to the Federal Food, Drug, and Cosmetic Act, involved here, which added to the types of misbranded drugs those of a toxic nature safe only on prescription of a physician. Act of October 26, 1951, 65 Stat. 648, 21 U. S. C. 353 (b), *supra*, p. 3.

of Congress to prevent the channels of interstate commerce from being used to the detriment of public health. To that end, the Court recognized in *Sullivan* that the Food and Drug Act was intended to extend its coverage "to every article that had gone through interstate commerce until it finally reached the ultimate consumer", 332 U. S. at pp. 696–697. The ruling that such coverage was constitutional is decisive here. No attack is or could be made on the reasonableness of the Congressional finding that certain drugs are too dangerous to be dispensed without prescription. The only issue is whether Congress has the right to follow the drug beyond the interstate shipment itself to the ultimate consumer. That question was decided affirmatively by *Sullivan*. See also *United States* v. *Walsh*, 331 U. S. 432, 434, 437–438; *United States* v. *Dotterweich*, 320 U. S. 277, 280; *McDermott* v. *Wisconsin*, 228 U. S. 115, 128.

CONCLUSION

For the foregoing reasons, we submit that this petition for a writ of certiorari should be denied.

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SEPTEMBER 1956.

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EDWARD KRAVETZ, MELBURN HOLTZMAN,
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vs.

UNITED STATES OF AMERICA,

Respondent.

REPLY OF PETITIONERS TO THE BRIEF FOR THE UNITED STATES IN OPPOSITION.

BERNARD H. SOKOL,
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The Scheffer Press, Inc.—ANdover 3-6850

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REPLY OF PETITIONERS TO THE BRIEF FOR THE UNITED STATES IN OPPOSITION.

What may be a misleading statement in the brief filed by the United States requires comment. On page 5 of the Brief in Opposition filed in behalf of the respondent, it is acknowledged that a factual distinction between the case of *United States* v. *Sullivan,* (332 U. S. 789), and the instant case exists. This factual difference, however, is so recharacterized that a misleading conclusion is drawn by the respondent. The issue in the *Sullivan* case concerned the lack of labeling *at the time of local sale to the purchasers.* No question was present concerning the nature of the labeling at the time the goods were placed in inter-state commerce by the manufacturer.

In the *Sullivan* case the purchasers were not given the information or directions for use prescribed by the manufacturer. In the instant case the manufacturer's labels were preserved intact and delivered to the purchasers on the bottles. The constitutional question in the *Sullivan* case was not the same because the misbranding, *i.e.*, the obliteration through removal of the label, was *actual*.

It is stated in the respondent's brief that when the Court held in the *Sullivan* case that Congress could prohibit the removal of labels, that it necessarily decided the question here. This statement flies in the face of the opinion of the Supreme Court. The majority opinion, as well as the minority opinion, devoted considerable space to consideration whether the removal of the labels was a violation of the law because Congress had a right to provide that the message of the manufacturer for the purposes of use be undisturbed.

The issue in the instant case does not lie in the question whether Congress may preserve the integrity of an article and its label. The issue is whether Congress can, in spite of and in addition to, legislation respecting the label, regulate conditions of local sale so as to require a physician's prescription. There is no justification for the conclusion drawn by the respondent, that the Supreme Court decided the question before us here. It has cited not one sentence from the decision of the Supreme Court in the *Sullivan case* which would support this view.

Had the Supreme Court considered that Congress could regulate conditions of local sale of drugs under the commerce power identical with that exercised under the power to tax, as in the case of narcotic legislation, it could easily

have said so and made short shrift of the constitutional question presented in the *Sullivan* case. This it did not do.

It is significant that the reply brief of the respondent in no way refers to the means used by Congress to regulate drugs in this instance. Nothing is said in justification of the technique wherein Congress has created a legal fiction in order to achieve its end, that is, calling a true label false for the purpose of imposing a criminal penalty.

Although it is doubtful that such was its intent, if the Supreme Court really meant in the *Sullivan* case that Congress had justification for the Durham-Humphrey amendment, then this is a perfect factual case in which the Supreme Court may exercise its jurisdiction and say precisely what the United States said it meant. If the Supreme Court did not, as your petitioners believe, then this Court should accept jurisdiction to correct a dangerous form of legislative abuse. The technique prescribed in the Durham-Humphrey amendment is a device which can be easily contrived to change the character of any act and bring it within the Federal jurisdiction contrary to law.

Respectfully submitted,

BERNARD H. SOKOL,
Attorney for Petitioners.